

# Reducing alcohol consumption

## *Comparing three brief methods in family practice*

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### ABSTRACT

**OBJECTIVE** To compare the effects of three brief methods of reducing alcohol consumption among family practice patients.

**DESIGN** Patients randomly assigned to one of three interventions were assessed initially and at 3-, 6-, and 12-month follow-up appointments.

**SETTING** Family practice clinic composed of 12 primary care physicians seeing approximately 6000 adults monthly in a small urban community, population 40000.

**PARTICIPANTS** Through a screening questionnaire, 134 men and 131 women were identified as hazardous drinkers (five or more drinks at least once monthly) during an 11-month screening of 1420 patients. Of 265 patients approached, 180 agreed to participate and 159 (83 men and 76 women) actually participated in the study.

**INTERVENTIONS** Three interventions were studied: brief physician advice (5 minutes), two 30-minute sessions with a physician using cognitive behavioural strategies, or two 30-minute sessions with a nurse practitioner using identical strategies.

**MAIN OUTCOME MEASURES** Quantity and frequency (QF) of drinking were used to assess reduction in hazardous drinking and problems related to drinking over 12 months of follow up.

**RESULTS** No statistical difference between groups was found. The QF of monthly drinking was reduced overall by 66% (among men) and 74% (among women) for those reporting at least one hazardous drinking day weekly at assessment (N = 96). Men reported drinking significantly more than women.

**CONCLUSIONS** These results indicated that offering brief, specific advice can motivate patients to reduce their alcohol intake. There was no difference in effect between brief advice from their own physician or brief intervention by a physician or a nurse.

### RÉSUMÉ

**OBJECTIF** Comparer les effets de trois types d'intervention brève visant à réduire la consommation d'alcool dans une clientèle de médecine familiale.

**CONCEPTION** Évaluation initiale et après 3 mois, six mois et 12 mois chez les patients assignés par randomisation à l'une des trois interventions.

**CONTEXTE** Clinique de médecine familiale composée de 12 médecins de première ligne qui voient mensuellement environ 6000 adultes dans une petite communauté urbaine de 40000 habitants.

**PARTICIPANTS** À partir d'un questionnaire de dépistage administré à 1420 patients sur une période de 11 mois, on a identifié 134 hommes et 131 femmes dont la consommation comportait des risques (minimum de cinq consommations au moins une fois par mois). Des 265 patients contactés, 180 ont accepté de participer ; de ce nombre 159 (83 hommes et 76 femmes) ont véritablement participé à l'étude.

**INTERVENTIONS** On a analysé trois types d'interventions : brève session de counselling par le médecin (5 minutes), deux sessions de 30 minutes par un médecin utilisant les stratégies cognitivo-comportementales et deux sessions de 30 minutes par une infirmière praticienne utilisant les mêmes stratégies.

**PRINCIPALES MESURES DES RÉSULTATS** Au cours d'un suivi de 12 mois, mesurer la quantité et la fréquence de la consommation afin de déterminer la réduction de la consommation à risque et les problèmes liés à la consommation.

**RÉSULTATS** Aucune différence statistique entre les groupes. Chez les participants qui avaient rapporté, lors de l'évaluation initiale, au moins une journée par semaine de consommation à risque (N = 96), on a constaté une réduction globale de la quantité et de la fréquence des consommations mensuelles de 66 % (chez les hommes) et de 74 % (chez les femmes). Les hommes ont rapporté consommer significativement plus que les femmes.

**CONCLUSIONS** Ces résultats montrent que des sessions brèves de conseils précis peuvent motiver les patients à réduire leur consommation d'alcool. On n'a pas constaté de différence entre l'efficacité des sessions brèves par le médecin personnel du patient et les interventions brèves par un autre médecin ou par une infirmière.

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**A**lcohol consumption and its consequences can be viewed along a continuum, on which "most people have no alcohol problems, many people have few problems, and a few people have many alcohol problems."<sup>1</sup> Outcome studies suggest that treatment is more effective, and of shorter duration, the earlier a person receives it.<sup>2</sup>

The point of entry into the health care system is usually through contact with a family physician. Although people with alcohol-related problems tend to use health care services more frequently than the general population,<sup>3-6</sup> alcohol-related treatment programs have traditionally been separated from general medical practice. Yet 90% of adult medical outpatients report using alcohol, and 45% report a history of excessive drinking consistent with "at risk drinking or dependence."<sup>7-9</sup> Many reports document that increasing health problems parallel the severity of alcohol abuse; excessive drinkers have an increased risk of injury,<sup>10</sup> have multiple health problems,<sup>11-13</sup> have double the mortality rate,<sup>14</sup> and use health care services at higher rates than those who drink moderately.<sup>15,16</sup>

An estimated 15% of family practice patients consume harmful amounts of alcohol.<sup>17</sup> Physicians are well situated to detect the signs of alcohol abuse and to intervene early without undue demands on their time.<sup>14,18,19</sup>

The review by Rush et al<sup>19</sup> indicates physicians vary greatly in approach to screening for alcohol use and dealing with problems relating to alcohol. The Alcohol Risk Assessment and Intervention project of the College of Family Physicians of Canada is an important advance in educating physicians.

We evaluated the effect of providing brief, specific information, together with strategies for reducing alcohol intake, to patients attending a family

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practice. Cognitive-behavioural strategies have been successful in several populations of problem drinkers.<sup>20-23</sup> All strategies are described by Sanchez-Craig and colleagues.<sup>2</sup>

## METHOD

### Screening procedures

Twelve physicians (six men and six women) at a family practice centre in a small city (population 40 000) agreed to have their patients screened on a weekly rotating schedule. Consecutive patients older than 15 years were approached by the attending nurse in the privacy of the examining room while waiting for appointments with their physicians. Patients were not selected by their physicians. Over an 11-month period, 1420 patients completed a brief questionnaire containing four CAGE<sup>24</sup> items and questions about alcohol consumption over the previous 28 days. The questionnaire was acceptable to patients and was used to identify patients for the study.<sup>25</sup>

### Study selection criteria

Upon completing the screening questionnaire, patients at risk were identified if they had responded positively to one or more CAGE items or had reported that they consumed four or more standard drinks on any day in the previous 28 days. The criterion of four or more drinks was used to ensure no individual was overlooked. Positive response to one CAGE item alone did not screen a patient into the program.

Of 134 male and 131 female patients identified, six men and 19 women answered yes to two or more CAGE questions without reporting a hazardous drinking day. Of the 265 patients contacted by telephone, 180 (68%) agreed to return for an appointment and 159 (60%) attended. The remainder, for various reasons, declined to participate or did not believe their drinking needed attention. Those who did not participate reported a greater mean of total drinking days during the previous 28 days ( $t$  [ $df=238$ ] = 2.41,  $P=.02$ ). They declined further contact for this study.

### Design

Patients were randomly assigned to one of three strategies: 5 minutes' advice from their own physicians, brief intervention by a physician, or brief intervention by a nurse practitioner. Advice from patients' family physicians (5 minutes) was considered minimal treatment (the control). Follow-up information was collected at 3, 6, and 12 months.

### Statistical method

A multivariate analysis of variance (MANOVA) with repeated measures was used to compare patient reports of alcohol consumption over four periods (assessment, 3-, 6-, and 12-month follow up), using two independent measures (sex and group). The dependent measure was quantity-frequency (drinks  $\times$  days), the mean monthly report (QF) given by the patient. A power analysis was conducted to determine the sample size. The estimated effect in reducing consumption was 10% for spontaneous reduction, 30% for brief advice, and 50% for the brief intervention. Assuming group means distributed evenly over this range, with the  $\alpha$  level set at  $P < .05$ , each group would require 50 subjects.

### Procedure

When patients arrived at the clinic for their scheduled appointments, they were interviewed by the research coordinator. They signed an agreement to participate and completed a lifestyle and substance abuse questionnaire. The first intervention or advice session followed immediately.

For the 5 minutes' advice, patients' family physicians used the patients' initial self-reports of drinking to give specific information on a standard drink, the limits of moderation, sensible drinking, and avoiding risky situations. Possible connections between drinking and the health concerns that prompted the office visit were identified. This advice was reinforced with a handout.

Dr Martha Sanchez-Craig, a psychologist at the Addiction Research Foundation, provided the initial on-site training, supplied the booklets, and reviewed videotaped practice interview sessions. The other physician and the nurse practitioner both offered two sessions 2 weeks apart, which included the basic information given in the brief advice, and helped patients understand the function of alcohol within their daily activities. A plan of action specifying a goal, developing strategies for moderation, and keeping daily drinking records was discussed. At the end of the first session, patients were given booklets containing this information and sheets on which to record their drinking.

## RESULTS

Of the 159 patients who kept their first appointments, 158 (99%) were located at 3 months', 148 (93%) at 6 months', and 143 (90%) at 12 months' follow up. No patient declined follow-up appointments, although some stated they had no need for further contact.

**Table 1. Patient characteristics at assessment (N = 159)**

PATIENT CHARACTERISTICS	TREATMENT GROUPS		
	PHYSICIAN INTERVENTION (N = 40)	NURSE PRACTITIONER INTERVENTION (N = 66)	BRIEF PHYSICIAN ADVICE (N = 53)
Men	23	37	23
Women	17	29	30
Mean age	30.7	31.8	30.6
Married or common-law	16	31	27
Single (unmarried, divorced, or widowed)	24	35	26
Employed full time	21	36	22
Employed part time	5	10	11
Unemployed	14	20	20
Previous alcohol treatment	2	2	1
Currently receiving mental health treatment	4	3	6
Daily alcohol use	6	7	2
Morning alcohol use	5	6	2
Family history of alcohol abuse			
• Grandparent	2	8	4
• Parent	6	21	18
• Sibling	4	6	9
• Other relative	3	2	5

Demographic and alcohol-related indices are given in **Table 1**. The three strategy groups did not differ ( $P > .10$ ) on these variables. Twenty-five percent of the patients scheduled for the physician and nurse practitioner interventions did not return for their second session scheduled 2 weeks later.

### 1-year outcome

Mean monthly QF was reduced significantly in the total sample (N = 143) for both men (47%) and women (37%) over the 12-month period (**Table 2**). There were no significant differences by group, but time, sex, and sex-time interactions were significant: time (F [ $df = 3, 125$ ] = 10.1,  $P < .000$ ), sex (F [ $df = 1, 137$ ] = 38.5,  $P < .000$ ), sex-time interaction (F [ $df = 3, 135$ ] = 2.86,  $P < .039$ ).

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**Table 2.** Monthly quantity-frequency of drinking reported by patients followed for 12 months (N = 143)

PATIENT GROUPS	ASSESSMENT	3-MONTH FOLLOW UP	6-MONTH FOLLOW UP	12-MONTH FOLLOW UP	OVERALL REDUCTION (%)
MEN					
Group 1	46.2	44.0	31.5	27.7	40
Group 2	51.0	37.0	24.7	22.9	55
Group 3	51.3	35.2	29.6	27.5	46
WOMEN					
Group 1	11.6	10.7	9.2	8.2	30
Group 2	24.2	14.2	12.8	10.6	56
Group 3	9.4	12.3	6.1	6.0	26

Group 1—physician intervention, group 2—nurse practitioner intervention, group 3—brief physician advice.

**Table 3.** Monthly quantity-frequency reports for clients reporting at least one hazardous (five or more drinks) drinking day at assessment followed through 12 months (N = 96)

PATIENT GROUPS	ASSESSMENT	3-MONTH FOLLOW UP	6-MONTH FOLLOW UP	12-MONTH FOLLOW UP	TOTAL (%)
MEN					
Group 1	56.2	55.2	31.5	26.6	59
Group 2	47.4	27.4	15.8	12.7	73
Group 3	56.1	30.8	25.9	20.4	64
WOMEN					
Group 1	11.1	5.0	3.0	2.3	79
Group 2	25.3	11.1	9.5	6.6	74
Group 3	11.8	6.9	5.8	3.9	66

Group 1—physician intervention, group 2—nurse practitioner intervention, group 3—brief physician advice.

The sex-time interactions were of statistical, rather than clinical, significance.

### Hazardous drinkers

Results at assessment compared with the original screening indicated that 106 of the 159 patients continued to report one or more hazardous drinking days. The remaining 53 patients reported cutting back on their drinking between screening and assessment. A further MANOVA was conducted on the remaining 106 patients (hazardous drinkers only, since this level of drinking was particularly targeted by the project). Of the 106 patients, 96 were followed through 12 months. Table 3 shows that these 96 patients (men 65%, women 73%) reported a greater reduction over the 12-month period: time ( $F [df=3,88] = 14.2, P < .000$ ), sex ( $F [df=1,90] = 23.2, P < .000$ ), sex-time interaction ( $F [df=3,88] = 3.62, P < .016$ ).

Inspection of hazardous drinkers' reports showed that nearly all patients reduced their alcohol intake, but very few eliminated all days of drinking at hazardous levels. However, taking the criterion of 48 drinks monthly for men (four drinks on three occasions weekly) and for women (three drinks on four occasions weekly) as acceptable levels, 31 men and six women reported drinking above this level at assessment. At 12-month follow up, 18 (58%) of these men and all six (100%) women reduced their monthly intake to below this criterion.

### Problems associated with drinking

Patients were described as problem-free if they had no more than one of the following physical or dependence symptoms. Physical symptoms included insomnia, headache, nausea, cramps, diarrhea,

palpitations, shakiness, sweats, poor memory, poor concentration, mood or personality changes, and feeling sluggish. Dependence symptoms included tremors when drinking had stopped, hallucinations, delirium tremens, seizures, drinking to relieve withdrawal symptoms, anxiety or panic when alcohol was unavailable, and an obsession with alcohol or a compulsion to drink. **Table 4** shows the proportion of problem-free patients at each follow-up period. Only one patient with missing reports was estimated to be problem-free, based upon his last report (at 3 months). Other missing patients were estimated as continuing to have problems (15% to 39% for men, and 22% to 53% for women). The frequency and number of symptoms were reported as reduced by most patients.

## DISCUSSION

This study investigated drinking patterns of family practice patients who might be at risk for developing problems associated with alcohol. Our study had several limitations. Alcohol consumption level was based on self-report and thus could have been underreported. However, underreporting should have been the same in all groups. This study used 28-day reports of alcohol consumption and thus, due to averaging, might have reported lower levels of consumption than 7-day reports in the Anderson and Scott study<sup>26</sup> and the ARAI recommendations<sup>27</sup> would have reported. Screening took place in offices, so it would not reach patients in nursing homes, those cared for at home, and the 25% to 30% of family practice patients who do not make yearly visits to a physician.

Patients who declined to participate in the study (32%) and those who agreed to return for an appointment, but did not, had a higher mean of total drinking days. Their physicians were not aware of this increase because of our anonymous screening. Other studies had a lower return rate (2% return of questionnaires and 29% eligible for the study by Anderson and Scott<sup>26</sup>; 1.1% return of questionnaires and 25% eligible for the study of Wallace et al<sup>28</sup>). We had a much higher return of questionnaires (97%) but a smaller number of patients eligible for the study (20%).

Our screening data showed that men drank more frequently at a higher level than women. Despite the fact that men and women were identified as drinking hazardously in about the ratio of 3:1, the overall effect of screening was to reach as many women as men, because women tend to visit their physicians more frequently.

This study offered information and specific strategies to patients who reported hazardous alcohol consumption or who identified problems associated with alcohol. The brief advice was intended as the minimum a physician should offer a patient once hazardous drinking was identified (the control group). Twenty-eight of 134 patients reporting hazardous drinking at screening had already cut back on their consumption, eliminating all hazardous days at assessment. This suggests that even a brief screening questionnaire is sufficient for some individuals to reflect on the level of their drinking. Those still reporting hazardous drinking at assessment reported

**Table 4. Percentage of patients categorized as problem-free at assessment and follow-up appointments**

TIME OF INTERVENTION	PROBLEM-FREE MEN (N = 83)	PROBLEM-FREE WOMEN (N = 76)
Assessment	12 (14.5%)	17 (22.4%)
3-month follow up	25 (30.1%)	38 (50.0%)
6-month follow up	29 (34.9%)	39 (51.3%)
12-month follow up	32 (38.6%)	40 (52.60%)

a steady decline over the 12-month follow-up period, but very few eliminated all hazardous days. Half of women and two thirds of men continued to report some (although fewer) problems associated with their drinking.

At 12-month follow up, Anderson and Scott<sup>26</sup> reported a reduction of 13% at-risk (male) drinkers attributed to their intervention. This group also had a greater reduction in the total sample (195 g of alcohol weekly), but a smaller reduction when attempting to determine the treatment effect. This group did not have a 3-month and 6-month follow-up contact to influence the determination of effect. The researchers did divide their control group into those with and without assessment with no difference in effect.

The study by Wallace et al<sup>28</sup> found a slightly greater effect of physician intervention than the Anderson and Scott study. At 1-year follow up, the treated group showed a mean reduction in consumption of alcohol of 180 g weekly versus a reduction of 80 g weekly in the control group.

In our study the effect was recorded in QF monthly. At 12 months the overall decrease for men was 47%.

Family practice, with its high patient return rate, is an ideal setting for ongoing outcome assessment as

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an integral part of the delivery of high-quality health care. The reactive effect of the follow-up process requires more systematic investigation, especially where minimal strategies are used.

## CONCLUSION

We found the different methods of presentation of brief strategies for reducing alcohol intake had similar effects. We expected that the two 30-minute sessions would be more effective than the 5-minute physician advice. The following conclusions can be drawn.

- Patients reacted to the screening and assessment tools, thus reducing overall alcohol consumption in the groups.
- The advice and pamphlet given by family physicians was more effective than originally predicted.
- Whether a physician or nurse delivered the brief intervention, the effect was the same.

Experts estimate that consumption of more than 12 alcoholic drinks weekly represents moderate risk for developing alcohol problems. Such drinking can cause problems, especially if drinking exceeds four drinks daily for men and three drinks daily for women. Drinking above this level provides physicians with sufficient reason to discuss patients' use of alcohol.

The effect of family physicians' giving brief advice on hazardous drinking could be considerable. Moreover, this type of intervention costs little and appears to be effective, at least in a 12-month follow-up period. ♦

## Acknowledgment

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## References

1. Marlatt GA, Larimer ME, Baer JS, Quigley LA. Harm reduction for alcohol problems: moving beyond the controlled drinking controversy. *Behav Ther* 1993;24:461-504.
2. Sanchez-Craig M, Wilkinson A, Walker K. Theory and methods for secondary prevention of alcohol problems: a cognitively based approach. In: Cox WM, editor. *Treatment and prevention of alcohol problems: a resource manual*. New York: Academic Press; 1987. p.287-331.
3. Rush B. The use of family medical practices by patients with drinking problems. *Can Med Assoc J* 1989;140:35-9.
4. Rush B, Brennan M. Is the health profile of problem drinkers different from that of other patients? *J Fam Pract* 1990;31:42-6.
5. Holder HD, Blose JO. Alcoholism treatment and total health care utilization and costs. A four-year longitudinal analysis of federal employees. *JAMA* 1986;256:1456-60.
6. Reiff S, Griffiths B, Forsythe AB, Sherman RM. Utilization of medical services by alcoholics participating in a health maintenance organization outpatient treatment program: three year follow-up. *Alcohol Clin Exp Res* 1981;5:559-62.
7. Buchsbaum DG, Buchanan RG, Centor RM, Schnoll SH, Lawton MJ. Screening for alcohol abuse using CAGE scores and likelihood ratios. *Ann Intern Med* 1991;115:774-7.
8. Cleary PD, Miller M, Bush BT, Warburg MM, Delbanco TL, Aronson MD. Prevalence and recognition of alcohol abuse in a primary care population. *Am J Med* 1988;85:466-71.
9. Coulehan JL, Zettler-Segal M, Block M, McClelland M, Schulberg HC. Recognition of alcoholism and substance abuse in primary care patients. *Arch Intern Med* 1987;147:349-52.
10. Skinner HA, Holt S, Schuller R, Roy J, Israel Y. Identification of alcohol abuse using laboratory tests and a history of trauma. *Ann Intern Med* 1984;101:847-51.
11. Puddy IB, Bellin LJ, Vandogen R. Regular alcohol use raises blood pressure in treated hypertension subjects: a randomized controlled trial. *Lancet* 1987;1:647-51.
12. Buchan IC, Buckley EG, Deacon GL, Irvine R, Ryan MP. Problem drinkers and their problems. *J R Coll Gen Practitioners* 1981;31:151-3.
13. Gill JS, Zezulda AV, Shipley MJ, Gill SK, Beevers DG. Stroke and alcohol consumption. *N Engl J Med* 1986; 315:1041-6.
14. Putnam S. Alcoholism, morbidity and care-seeking: the inpatient and ambulatory service utilization and associated illness experience of alcoholics and matched controls in a health maintenance organization. *Med Care* 1982;20:97-121.
15. Klatsky AL, Friedman GD, Siegelaub AB. Alcohol and mortality. A ten-year Kaiser-Permanente experience. *Ann Intern Med* 1981;95:139-45.
16. Roghmann KJ, Roberts JS, Smith TS, Wells SM, Wersinger RP. Alcoholics' versus nonalcoholics' use of services of a health maintenance organization. *J Stud Alcohol* 1981; 42:312-22.

17. Malla A, Merskey H. Screening for alcoholism in family practice. *Fam Pract Res J* 1987;6:138-47.
18. McIntosh MC, Sanchez-Craig M. Moderate drinking: an alternative treatment goal for early-stage problem drinkers. *Can Med Assoc J* 1984;131:873-6.
19. Rush B, Ellis K, Crowe T, Powell L. How general practitioners view alcohol use. Clearing up the confusion. *Can Fam Physician* 1994; 40:1570-9.
20. Sanchez-Craig M, Annis HM, Bornet R. Random assignment to abstinence and controlled drinking: evaluation of a cognitive-behavioral program for problem drinkers. *J Consult Clin Psychol* 1984; 52:390-403.
21. Sanchez-Craig M, Leigh G, Spivak K, Lei-H. Superior outcome of females over males after brief treatment for the reduction of heavy drinking. *Br J Addict* 1989; 84:395-404.
22. Sanchez-Craig M, Spivak K, Davila R. Superior outcome of females over males after brief treatment for the reduction of heavy drinking: replication and report of therapist effects. *Br J Addict* 1991;86:867-76.
23. Sanchez-Craig M, Davila R, Cooper G. A self-help approach for high risk drinking: effect of an initial assessment. *J Consult Clin Psychol* 1996;64:694-700.
24. Mayfield D, McLeod G, Hall P. The CAGE questionnaire: validation of a new alcoholism instrument. *Am J Psychiatry* 1974;131:1121-3.
25. McIntosh MC, Leigh G, Baldwin NJ. Screening for hazardous drinking. Using the CAGE and measures of alcohol consumption in family practice. *Can Fam Physician* 1994;40:1546-53.
26. Anderson P, Scott E. The effect of general practitioners' advice to heavy drinking men. *Br J Addict* 1992;87:891-900.
27. College of Family Physicians of Canada. *Alcohol Risk Assessment and Intervention (ARAI)*. Mississauga, Ont: College of Family Physicians of Canada; 1994.
28. Wallace P, Cutler S, Haines A. Randomized control trial general practitioner intervention in patients with excessive alcohol consumption. *BMJ* 1988;297:663-8.

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# Engerix-B

(HEPATITIS B VACCINE [Recombinant])

## Delivering rapid antibody response and protection.

### INDICATIONS AND CLINICAL USE

Engerix-B (hepatitis B vaccine [recombinant]) is indicated for active immunization against hepatitis B virus infection. The vaccine will not protect against infection caused by hepatitis A and non-A, non-B hepatitis viruses. As hepatitis D (caused by the delta agent) does not occur in the absence of hepatitis B infection or carrier state, it can be expected that hepatitis D will also be prevented by vaccination with Engerix-B. The vaccine can be administered at any age from birth onwards. It may be used to start a primary course of vaccination or as a booster dose. It may also be used to complete a primary course of vaccination started with plasma-derived or yeast-derived vaccines or as a booster dose in subjects who have previously received a primary course of vaccination with plasma-derived or yeast-derived vaccines.

In areas of low prevalence of hepatitis B, vaccination is strongly recommended in subjects who are at increased risk of infection.

### CONTRAINDICATIONS

Hypersensitivity to any component of the vaccine. As for any vaccine, Engerix-B (hepatitis B vaccine [recombinant]) should not be administered to subjects with severe febrile infections. Vaccination of a subject with febrile symptoms, with a respiratory infection, or with a contagious or any other disease should be postponed until after recovery. However, the presence of a trivial infection does not contraindicate vaccination.

### WARNINGS

Because hepatitis B has a long incubation period it is possible that there may be latent infection at the time of vaccination. Hepatitis B vaccine [recombinant] may not prevent hepatitis B in such cases.

Patients who develop symptoms suggestive of hypersensitivity after an injection should not receive further injections of Engerix-B (see CONTRAINDICATIONS). Engerix-B should not be administered in the gluteal region or intradermally since these routes of administration may not result in an optimum immune response. Intradermal administration may also result in severe local reactions. The vaccine must never be administered intravenously.

In dialysis patients and subjects who have an impairment of the immune system, adequate antibody concentrations may not be maintained after a primary vaccination course of 40 µg doses. Such patients may therefore require repeated administration of the vaccine. The immune response to hepatitis B vaccines is related to a number of factors, including older age, male gender, obesity, smoking habits and route of administration. In subjects who may respond less well to the administration of the hepatitis B vaccine (e.g., more than 40 years of age, etc.), additional doses may be considered.

### PRECAUTIONS

A new sterile syringe and a new sterile needle should always be used so as to prevent the transmission from one subject to another of infectious agents, such as the hepatitis B virus, non-A, non-B hepatitis virus or the human immunodeficiency virus (HIV).

**Pregnancy:** The effect of the antigen on fetal development is unknown and, therefore, vaccination of pregnant women cannot be recommended. However, vaccination of a pregnant woman may be considered in order to prevent hepatitis B in high-risk situations.

As with all biologicals, a solution of 1 in 1,000 adrenaline should always be readily available for immediate use in case of a rare anaphylactic reaction.

### ADVERSE REACTIONS

Engerix-B (hepatitis B vaccine [recombinant]) is generally well tolerated.

The most frequently occurring adverse events, usually mild and transient, are associated with the injection site and include soreness, erythema and induration.

### DOSAGE

**Schedule:** The recommended schedule is 3 doses administered at 0, 1 and 6 months. For more rapid protection, a 4 dose schedule (0, 1, 2 and 6 months) results in the development of protective anti-HBs titres by 3 months. The fourth dose (at 12 months) is required to maintain prolonged, protective anti-HBs titres.

**Adults 20 years and over:** A dose of 20 µg of antigen protein in 1 mL suspensions.

**Neonates, infants, children and adolescents up to 19 years:** A dose of 10 µg of antigen protein in 0.5 mL sus-

pension. If compliance to the full 0, 1, 6 month schedule cannot be assured in 11 to 19 year old adolescents, a 20 µg dose should be used to ensure seroprotection. When the pediatric presentation is not available, other presentations may be used for withdrawing the appropriate dose.

### Hemodialysis and immunocompromised patients:

A 2 mL dose of Engerix-B (40 µg) is recommended.

### VACCINATION SCHEDULES

	3-Dose Schedule	4-Dose Schedule	Hemodialysis Patients
<b>TIMING OF DOSES</b>			
1st dose	Zero time	Zero time	Zero time
2nd dose	1 month after 1st dose	1 month after 1st dose	1 month after 1st dose
3rd dose	6 months after 1st dose	2 months after 1st dose	2 months after 1st dose
4th dose	—	12 months after 1st dose	6 months after 1st dose

For more rapid protection, a 4-dose schedule results in the development of protective anti-HBs titres by 3 months. The fourth dose (at 12 months) is required to maintain prolonged protective anti-HBs titres.

**Booster doses:** After the 0, 1, 6 month primary immunization schedule, a booster dose will probably not be required earlier than 5 years after the primary course. For hemodialysis and immunocompromised patients, a booster (40 µg) may be required sooner. Regular serological monitoring is recommended to ensure that antibodies are and remain at protective levels.

### ADMINISTRATION

Check the expiry date of the vaccine carefully. Do not use vaccine beyond its expiry date. Shake the vaccine well before use so as to resuspend the sediment of fine white particles of adjuvant (aluminum hydroxide) which settles during storage.

**Engerix-B should be injected intramuscularly.** In adults the injection should be given in the deltoid region. In neonates and infants it may be preferable to inject Engerix-B in the anterolateral thigh because of the small size of their deltoid muscle. In special circumstances the vaccine may be administered subcutaneously in patients with severe bleeding tendencies (e.g., haemophiliacs).

**Engerix-B must not be given intravenously or intradermally.** Engerix-B may be administered simultaneously with hepatitis B immunoglobulin (HBIG); however, it must be administered at a separate injection site.

### AVAILABILITY OF DOSAGE FORMS

Engerix-B (hepatitis B vaccine [recombinant]) is available in four size formats, all containing the same formulation. Each 1 mL of vaccine contains 20 µg of hepatitis B surface antigen adsorbed onto 0.5 mg of Al<sup>+++</sup> as aluminum hydroxide. Engerix-B contains 0.005% thimerosal as preservative.

0.5 mL single pediatric dose vial containing 10 µg of hepatitis B surface antigen per vial in a carton with Prescribing Information leaflet.

1 mL adult dose vial containing 20 µg of hepatitis B surface antigen per vial in a carton with Prescribing Information leaflet.

For mass immunization programs, a 5 mL multi-dose vial containing 100 µg of hepatitis B surface antigen per vial and a 10 mL multi-dose vial containing 200 µg of hepatitis B surface antigen, each in a carton with Prescribing Information leaflet.

**Full prescribing information available on request.**

### REFERENCES:

1. Huston P. Perception of risk. *Can Med Assoc J* 1993; 149(10): p.1367.
2. Treadwell TL, et al. Immunogenicity of Two Recombinant Hepatitis B Vaccines in Older Individuals. *Am J Med* 1993; 95:584-588.
3. Dahl-Hansen E, et al. Immunogenicity of yeast-derived hepatitis B vaccine from two different producers. *Epidemiol Infect* 1990; 104: pp 143-149.
4. Greenberg DP, et al. Comparative Safety and Immunogenicity of Two Recombinant Hepatitis B (HBV) Vaccines Given to Infants 2, 4 and 6 Months of Age. *Pediatr Infect Dis J* 1996; 15:590-6.

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VACCINES

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